Norman M. Black III
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404-428-1813

K072124

510(k) Summary of Safety and Effectiveness

JAN 18 2008

1. Submitter Information

Norman M. Black III d/b/a Black and Black Surgical, Inc.
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Atlanta, GA 30345
Contact: Norman Black
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Date summary prepared: August 1, 2007

2. Name of Device

Trade or Proprietary Name: Black and Black Electrosurgical Cutting and Coagulation Forceps and Electrodes

Common Name: Monopolar electrosurgical device

Classification Name: Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, GEI, General and Plastic Surgery

3. Predicate Devices

The Black and Black Surgical monopolar forceps and electrodes are substantially in function and intended use to the Colorado MicroDissection Needle (K033232), Valleylab Bayonet Forceps, Conmed Bayonet Straight Tip with Cable, Snowden-Pencer Endo-Plastic Electrosurgical Dissector, Snowden-Pencer Monopolar Insulated Forceps, and Olsen Hand Activated Monopolar Forceps. All devices are used for monopolar electrosurgery, allowing the surgeon to actuate the electrosurgical generator from the sterile field using either push button controls or a foot switch on the device.

4. Device Description

The Black and Black monopolar forceps and electrodes are handheld, reusable devices designed to deliver monopolar RF electrosurgical energy to a surgical site to cut and/or coagulate tissue.

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(Device Description continued)

The surgeon activates the desired electrosurgical mode from the sterile field by using buttons on the device. Three electrosurgical modes are available:

- Cut: cuts tissue with minimal coagulation / hemostasis
- Hemostasis with Division: divides tissue with controlled hemostasis
- Coag: coagulates bleeding vessels to promote hemostasis

5. Intended Use

The Black and Black monopolar forceps and electrodes are reusable devices intended for use in surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic, arthroscopic) where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate tissue.

There are no specific contraindications associated with the Black and Black monopolar forceps and electrodes.

6. Summary of Technological Characteristics

The Black and Black monopolar forceps and electrodes have the same basic technological characteristics as the predicate devices noted above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Black & Black Surgical, Inc.
% Mr. Norman Black
President
2759 Hawthorne Drive
Atlanta, Georgia 30345

Re: K072124
Trade/Device Name: Black and Black Electrosurgical Cutting and Coagulation Forceps and Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: December 05, 2007
Received: December 06, 2007

Dear Mr. Black.:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (K072124):

Device Name: Black and Black Electrosurgical Cutting and Coagulation Forceps and Electrodes

Indications For Use:

The Black and Black Surgical monopolar electrodes and forceps are reusable devices intended for use in surgical procedures (such as general, urologic, thoracic, plastic and reconstructive, gynecologic, arthroscopic) where the surgeon desires monopolar radio-frequency electrosurgical energy to cut and/or coagulate soft tissue.

Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072124